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THE EFFECTS OF ATHLETIC MOUTH PROTECTORS  
UPON WORK OF BREATHING DURING EXERCISE

A

THESIS

Presented to the Faculty of  
The University of Texas  
Graduate School of Biomedical Sciences  
at San Antonio  
in Partial Fulfillment  
of the Requirements  
for the Degree of  
MASTER OF SCIENCE

By

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San Antonio, Texas

June, 1989

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THE EFFECTS OF ATHLETIC MOUTH PROTECTORS UPON  
WORK OF BREATHING DURING EXERCISE

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DEDICATION

This thesis is dedicated to my father, Robert D. Phoenix, Sr. He was my teacher, my toughest critic, and my staunchest supporter.

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I would like to acknowledge Dr. William J. Gibbons (Assistant Professor of Medicine, Pulmonary/Critical Care Division; and Medical Director, Pulmonary Function Laboratories, Medical Center Hospital) for serving as my research advisor. Dr. Gibbons provided valuable expertise, guidance, and support throughout the research effort.

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THE EFFECTS OF ATHLETIC MOUTH PROTECTORS  
UPON WORK OF BREATHING DURING EXERCISE

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at San Antonio

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In 1962, the first large-scale mandatory mouth protector rule was put into effect by the National Alliance Football Rules Committee. The regulation affected nearly one million athletes in high school, junior college, and college football programs.

Since that time, numerous athletic leagues have adopted similar rules covering a wide variety of sports. Consequently, an estimated two million athletes are affected by mouth protector regulations each year.

Accompanying the growth in coverage there has been growing concern over possible physiological effects produced by commonly-used mouth protectors. One of the major points

of this controversy has been the contention that athletic mouth protectors may be responsible for a significant increase in the work required for respiration (i.e. work of breathing). It has been argued that if such a relationship exists, mouth protectors could affect respiratory musculature, ventilation, and ultimately exercise performance.

A review of the literature indicates that all studies regarding the effects of mouth protectors upon work of breathing have been subjective (via survey). In addition, the results have been mixed.

The current investigation was undertaken to provide objective results regarding the effects of representative athletic mouth protectors upon work of breathing during exercise.

Eight normal males were chosen for participation in this investigation. Participants were issued each of the following types of commonly-available athletic mouth protectors:

- 1) Mouth-formed maxillary arch mouth protector
- 2) Mouth-formed maxillary/mandibular arch mouth protector
- 3) Custom-formed maxillary arch mouth protector

Following the distribution and fitting of the mouth protectors, each participant was scheduled for clinical exercise testing.

Experimental design required the presence of an esophageal balloon catheter during the exercise protocol. Following placement of the catheter, the participant was assigned one of the following independent variables:

- 1) No mouth protector (control measurement)
- 2) Mouth-formed maxillary arch mouth protector
- 3) Mouth-formed maxillary/mandibular arch mouth protector
- 4) Custom-formed maxillary arch mouth protector

The order of assignment was determined via random sequence.

With the appropriate mouth protector in position, the subject was asked to perform 10 minutes of bicycle ergometer exercise at 40 percent of the predicted maximum workload. Minute ventilation, oxygen consumption, carbon dioxide production, and end-tidal  $\text{pO}_2$  and  $\text{pCO}_2$  were monitored to indicate the onset of steady metabolic state exercise.

When a steady metabolic state had been reached, values for intrathoracic pressure and airflow at the mouth were recorded. Sampling of these parameters was accomplished in 30-second time blocks. Two samples were taken to verify reproducibility of these measurements.

Following the prescribed course of exercise, the mouthguard (none in the case of control measurement) was removed and the participant was instructed to rest for a period of 20 minutes. Respiratory rate, heart rate, and blood pressure were monitored to ensure that all values

returned to pre-exercise levels.

When the allotted time had passed, another independent variable was assigned for testing. The participant was directed to repeat the exercise protocol. This sequence was repeated until all independent variables had been tested.

Subsequently, results were used to calculate mean esophageal pressures for each participant exercising under each investigative condition. Because changes in mean esophageal pressure are directly proportional to changes in flow-resistive work of breathing per liter minute ventilation, this measurement was used as the basis for analysis.

Results were categorized according to the independent variable being tested (i.e. no mouth protector, mouth-formed maxillary arch mouth protector, mouth-formed maxillary/mandibular arch mouth protector, and custom-formed maxillary arch mouth protector). Individual means were calculated. Subsequently, these values were used to calculate group statistics.

Group means were compared using the repeated measures analysis of variance. This design revealed a significant difference at the 0.05 level.

To determine the exact nature of the difference, Fisher's least significant difference analysis was employed. Results indicated that mean esophageal pressure for control

(no mouth protector) differed from all remaining treatments (i.e. mouth-formed maxillary arch mouth protector, mouth-formed maxillary/mandibular arch mouth protector, and custom-formed maxillary arch mouth protector) at the 0.05 level. In addition, this analysis indicated the mean esophageal pressures for the custom-formed and both mouth-formed protectors were statistically similar.

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## I. INTRODUCTION

During the past several years, there has been a growing controversy over the physiological effects of commonly available athletic mouth protectors. One of the major points of this controversy has been the contention that athletic mouth protectors may produce a significant increase in the energy required for breathing (work of breathing).(1-5). If such a relationship exists, mouth protectors could affect the respiratory musculature, ventilation, and ultimately exercise performance. (6,7)

Prior to the 1960s, the use of intraoral protective devices in contact sports was largely at the discretion of individual competitors. Then in 1962, the first large scale employment of a mandatory mouth protector rule was put into effect by the National Alliance Football Rules Committee.(1,8-12) In 1973, the National Collegiate Athletic Association (NCAA) adopted a similar rule for NCAA football competition.(12-14) Since that time, the scope of the mandatory mouth protector rule has been expanded to involve other contact sports.(15) Currently, it is estimated that over two million athletes are affected by these rules.(16)

As a result of increased demand, several types of mouth protectors are available. These appliances may be divided

into three general categories based upon their respective properties. The categories are: 1) custom formed - fabricated over a dental cast of the player's mouth, 2) mouth formed - molded directly over the arch in the player's mouth, and 3) stock - ready-made and intended to fit any arch.(1,2,13,14,17-35)

A review of the literature indicates that all studies regarding the effects of mouth protectors upon work of breathing have been subjective (via survey).(1-5)

Furthermore, the results of these studies have been mixed. According to a report of the Bureau of Dental Health Education and Bureau of Economic Research and Statistics comparing the three classes of mouth protectors, "Some interference with breathing was experienced by 21 per cent of the players while wearing the custom made mouth protector, 44 per cent while wearing the mouth-formed, and 51 per cent while wearing the stock type."(2) Additional studies in this area seem to support such a relationship.

(3,4) A survey by Gee indicated that among the reasons given by players for not wearing mouth protectors, nearly half reported difficulty in breathing as a contributing factor.(3) Conversely, a study by de Wet indicated that only about 4 per cent of subjects reported difficulty in breathing.(5)

This investigation was undertaken to provide objective results regarding the effects of representative mouth

protectors upon work of breathing. Significant results could determine which mouth protector would offer the least airflow resistance, and determine which appliance would be most suitable for use during exertion.

## II. LITERATURE REVIEW

### THE HISTORY OF MOUTH PROTECTORS IN CONTACT SPORTS

For centuries, contact sports have been a source of enjoyment to both participant and spectator. As new games and contests were initiated, new types of protective equipment were developed to minimize potential injuries.

(36)

Today, the evolution of protective equipment continues. Greater understanding of physiology and sports medicine have provided insight into the causes of injury. Such insight has been instrumental in the development of improved protective equipment. Improved knee braces and flak vests have become standard equipment among NFL quarterbacks. Protective eyewear also has become evident among athletes in a wide variety of sports. These represent but a few examples of the advances in "athletic armor."

Few pieces of protective equipment, however, have been employed as successfully as the athletic mouth guard.

Historically, the person responsible for development of the first mouth guard is not known. According to Nat Fleischer, editor of The Ring magazine, the first mouth protector was used in 1913 by Ted "Kid" Lewis, an English boxer.(37) Lewis reportedly liked the protector so well that he continued to use it despite protests filed by

opposing managers and boxing commissions. Eventually, other English boxers followed Lewis' example, and the mouth protector slowly gained acceptance.(37,38)

Apparently, it took some time for news of the protective mouth guard to reach the United States. The first evidence of such a protector in U.S. dental literature was reported in 1930.(39-42)

At about the same time, research concerning injuries in interscholastic football was beginning. Early evidence indicated that there were many injuries to the teeth, varying from chipping to displacement. Despite such evidence, efforts for improved protective equipment were concentrated on helmets and shoulder pads.(9)

For approximately 10 years, little was written about oral injuries sustained in contact sports. Then, in 1941, Dr. Leon Kramer published a report of injuries sustained by high school athletes enrolled in the Athletic Accident Benefit Plan. Of 11,500 athletes, 691 reported injuries which required medical or dental attention. Of the 691 injuries, 184, or 27 per cent were dental injuries.(43) Apparently, the evidence was overlooked.

In the 1950s, contact sports received increasing attention. Unfortunately, as the number of participants grew so did the prevalence of oral injuries. A survey conducted by the University of Missouri involving 4,000 college athletes in 62 major colleges and universities,

indicated that dental injuries ranked ahead of other types of injuries in college football during the 1950 football season.(44)

In 1952, Cathcart published the results of a joint survey performed in Michigan, Wisconsin and Minnesota. The survey indicated that 52 per cent of injuries to high school football players occurred in the region of the mouth, lips, teeth or jaws.(45)

Although the need for oral protective devices was becoming painfully evident, dental professionals lacked one ingredient necessary to effect change ... public support. That support came in September of 1952 when Life magazine published photographs of the "toothless" Notre Dame football team.(46)

Suddenly, there was heightened interest in the topic of oral protective devices. Researchers and practitioners began to develop and test extraoral (faceguard) and intraoral (mouthguard) protective devices.(37,45,47,48) Authors such as Cathcart and Dukes reported the successful employment of mouthguards among small populations of high school football players.(37,45,47,49) But availability of guards was limited and their use was optional.

Due to the limited use of face and mouth guards, the results of injury surveys in the mid-1950s were nearly identical to those which had preceded. In the 1954-1955 Handbook of the National Federation of High School Athletic

Associations, football injuries were listed as follows: face and dental, 53.9 per cent; knee, 19.6 per cent; shoulder, 13.7 per cent; head, 9.7 per cent; and pelvic, 3.7 per cent.(50) Consequently, the search for effective mouth protection continued.

A 1955 Wisconsin study involving 303 high schools and over 15,000 players indicated that face guards (face masks) eliminated about one-half of oral injuries sustained during football competition.(2,32,51,52) The results of the study were so encouraging that in 1957 the National Federation Football Rules Committee recommended that every competitor wear a face protector.(9) In 1960, the committee made the face protector a mandatory piece of equipment.(2)

The impact of the mandatory face protector rule was quite impressive. A survey of dental claims made to the New York State High School Athletic Protection Plan showed a 53 per cent decline in oral injuries following the introduction of the mandatory face protector.(53) Still, the oral injury rate remained unacceptably high.

A 1960 study by the Wisconsin Interscholastic Athletic Association of some 24,000 high school football players showed that 20 per cent of such injuries affected the mouth and teeth. Although this number of injuries was considered deplorable, it was a tremendous improvement over conditions which prevailed prior to institution of the mandatory face protector rule.(8)

At the college level, the news was equally disappointing. A survey by Banks during the 1959-1960 football season indicated that among 3,694 football players there were 586 teeth lost, broken or chipped. Banks added that among these 586 dental injuries, 170 required prosthetic tooth replacement.(54)

The mandatory face mask ruling, although a step in the right direction, proved only partially effective in minimizing oral injuries. It was discovered that face guards primarily provided protection from direct blows to the mouth and other facial structures. Face guards did not protect the mouth from blows to the chin, nor did they protect from blows to the top of the head which might cause the jaws to snap shut. (12,55-58)

Fortunately, several practitioners and researchers had pursued the development and testing of intraoral mouth protectors.(48,58-60) The results of their investigations indicated a significant decrease in the number and severity of oral injuries when mouth protectors were used in conjunction with face protectors.(48,58-60)

Meanwhile, professional health organizations joined the effort. In 1960, the Joint Committee of the American Dental Association (ADA) Bureau of Dental Health Education and the American Association for Health, Physical Education and Recreation was formed. The committee conducted a literature review of football injuries, concluding that the incidence

of oral injuries remained altogether unacceptable.(52) The findings and recommendations of this group were central to the impending push for a mandatory mouth protector rule.(61)

Armed with a wealth of statistics and information, the American Dental Association launched an information campaign to educate both its members and the general public. Furthermore, the ADA went on record as a leading proponent in support of mandatory mouthguard regulations.(52)

In 1960 the American Dental Association House of Delegates passed resolutions "to make mouth protectors mandatory for body contact sports," and urged members of the dental profession "to cooperate with schools in developing mouth protector programs...mutually satisfying to the schools and the dentists."(62)

During the following year, the hopes of the ADA were realized. In 1961, the National Alliance Football Rules Committee introduced a regulation making mouth protectors mandatory for the 1962 season.(1,8-12) The rule stated, "Each player shall wear an intra-oral mouth and tooth protector which includes both an occlusal and labial portion. It is recommended that the protector be: (1) constructed and fitted to the individual by impressing his teeth into the mouth and tooth protector itself; or (2) constructed from a model made from an impression of the individual's teeth."(1,10,63)

To fully appreciate the scope of this ruling, one must

take into account that the National Alliance Football Rules Committee made the rules which governed contests played by members of the National Federation of High School Athletic Associations, the National Association of Intercollegiate Athletics, and the National Junior College Athletic Association.(12,61-64) Numerically, this equated to nearly one million athletes per year.(12,61,65)

As with any ruling of such magnitude, the emergence of benefits and difficulties was soon to follow. Though mouth guards were not new, the selection, processing and adaptation of large numbers of guards was new. Practically all individuals involved - coaches, dentists, and players - were not only being introduced to a new rule, but to the problems and methods by which mouth guards were to be obtained and fitted.(4) Barriers were encountered, and solutions found. The learning process was in full swing.

It was not long before feedback was available. Players cited difficulties which they had encountered in wearing the new devices. Among the difficulties most often cited were difficulty in breathing, discomfort, dry mouth (xerostomia), impaired speech, lack of retention and lack of durability.(2-5,63,66,67)

Athletic directors, coaches, and trainers also expressed opinions. These personnel tended to minimize the dental aspect and magnify the cost and discomfort of protective mouthguards.(69-72)

Indeed, there was a strong movement to rescind the mouth protector requirement.(26) Members of the National Alliance Football Rules Committee promised that a review of the mandatory mouth protector rule was forthcoming. All of the aforementioned factors would be considered, but the key to the continued existence of the mandatory mouth protector rule would be the success or failure of mouth guards in preventing oral injuries.(26)

At the 1962 meeting of the National Alliance Football Rules Committee, the evidence was presented. Following a review and discussion, the members of the committee voted to retain the mandatory mouth protector regulation.(26)

Soon, high school athletic associations not governed by the National Alliance adopted mandatory mouth protector regulations of their own.(73)

Although members of the dental profession breathed a collective sigh of relief, there was no time for relaxation. Immediately, attentions were turned to improvements in logistics, materials, and methods of fabrication.

The dental literature of the early 1960s became an important forum for sharing pertinent information. Terms were defined. Methods and ideas were shared. Problems and solutions were presented.

The categorization of mouth guards was an important stage in this process. Categorization provided researchers and practitioners with a "common language" - a basis for

effective communication. Mouth guards were (and are) categorized as follows:

- 1) Custom formed - fabricated over a dental cast of the player's mouth
- 2) Mouth formed - molded directly over the arch in the player's mouth
- 3) Stock - ready-made and intended to fit any arch  
(1,2,13,14,17-35)

Literature dealing with the fabrication of mouth guards also was in demand. That demand was answered with an abundance of technique articles.(27-37,49,70,74-95) The majority of articles prior to 1965 dealt with variations of the layered-latex mouth guard technique.(30-33,37,70,75,76,92-94) During the mid 1960s, the focus shifted to the fabrication of vacuum-formed vinyl custom guards.(36,86-90)

There was also literature dealing with the fitting and adjustment of mouth-formed guards.(28,29,79-81)

In the scientific community it was a time of materials testing. Mouth guard materials were pulled, stretched, snapped, struck and soaked.(96-102) New materials were developed and tested. Latex mouth guard materials were being replaced by vinyl materials.

Polyvinylacetate-polyethylene was rapidly becoming the material of choice for mouth guards.(96,98-101)

In research facilities, the first human studies were

being performed. Hickey et. al. were attempting to determine the effects of mouth protectors upon intracranial pressures and bone deformation. To accomplish this, the investigators devised an ingenious protocol. An impact producing mechanism was attached to a football helmet so that a blow of controlled force could be delivered to the inferior border of the chin of a male cadaver. Intracranial pressure and deformation were measured without a mouth protector in place, and with each of two types of mouth protectors in place. The researcher found there was a significant reduction in the amplitude of the intracranial pressure wave when a mouth protector was in place. Furthermore, bone deformation was decreased.(103)

Combined with the results of an earlier study by Gurdjian, the results obtained by Hickey et. al. indicated that mouth guards might be instrumental in the prevention of concussions.(103,104) This assumption seems to have been borne out in a five-year study conducted at Notre Dame University. In this study, Stenger et. al. reported a significant decrease in the number and severity of concussions following the introduction of intraoral mouth protectors.(105)

As the aforementioned studies were being conducted, investigations continued into the relationship between intraoral mouth guards and the incidence of oral injuries. Evidence gathered in the United States and abroad indicated

that oral injuries in contact sports were on the decline.(27,61,81,106-113)

Among the benefits recognized by national, state and local dental organizations was the tremendous public relations appeal of mouth protector programs. Dental organizations urged members to donate their skills in the spirit of community service. Reports of such efforts filled the dental literature of the period.(10,25,37,48,69,114-131)

The American Dental Association was not satisfied with the status of mouth protection in contact sports, however. As a result, the organization set it's sights on the largest remaining athletic association without a mandatory mouth protector rule ... the National Collegiate Athletic Association (NCAA).(61,62)

Despite overwhelming statistical evidence and the constant urging of the American Dental Association, the NCAA rejected the mandatory mouth protector regulation for several years.(62) Then in 1972, the NCAA introduced a mandatory mouth protector rule which would become effective during the 1973 season.(12-14) NCAA Rule 1-4-4 mandated that all players wear "professionally manufactured" equipment "not altered to decrease protection," including an "intraoral mouthpiece that covers all upper jaw teeth."(24)

This regulation added another 33,000 players to the roles of athletes covered by mandatory mouth protector rules.(14,65) With the introduction of this regulation, the

number of athletes covered by mandatory mouth protector rules exceeded one million.(12,14,100,132)

In 1973, the Baltimore Colts became the first National Football League (NFL) team to provide custom mouth protectors for all players. The use of mouth protectors became a mandatory Colt regulation.(133)

Throughout the 1970s, the development of protective equipment was fueled by advances in materials and designs.(57,134)

Injury studies were conducted to determine the statistical impact of oral protective devices. By the early 1980s, mouth protectors used in conjunction with helmet-attached face guards had reduced oral injuries to less than 0.5%.(135,136)

Although football traditionally had been the focus of interest and research concerning mouth protection, most other sports had not been evaluated.(132) This, too, was soon to change.(137,138)

Impressed by results attained in football, the Canadian and U.S. Amateur Hockey Associations instituted mouth guard requirements for their players in 1979. The NCAA instituted a similar rule in 1980.(15)

Mandatory mouth protector regulations soon spread to other sports. The Big Ten Conference made mouth protectors mandatory for female field hockey players in 1982.(15)

As the trend of mandatory mouth protection continued,

so did research efforts. Studies involving rugby and football were undertaken and results published. Once again, the effectiveness of intraoral mouth protection was verified.(69,132,139,140)

Researchers evaluated the physical properties of commonly available mouthguard materials. As before, polyvinylacetate-polyethylene proved to be the material of choice for custom-formed mouth protectors.(97,98)

Despite the wealth of information regarding materials and the effectiveness of mouth protectors in preventing oral injury, little had been done regarding the physiological effects produced by mouth protectors. Then, in 1982, Luke et. al. published the results of a pilot study dealing with the effects of mouth guards upon airflow. Five male athletes participated in the investigation. Each participant was asked to perform three levels of bicycle ergometer exercise with a mouth-formed mouth protector in place. Then each subject was asked to perform the same levels of bicycle ergometer exercise without the mouth protector. As participants exercised under each of these conditions, investigators monitored and recorded inspiratory airflow volumes. Subsequent statistical analyses indicated that mouth guards significantly impaired oral and total airflow, particularly at low levels of work.(141)

Research not only provided answers, but prompted further questions. As a result, there was a new surge of

interest in mouth protectors.

This surge of interest involved not only dentists and athletes, but also team physicians and athletic trainers.(38) In 1983, concern with all aspects of sports dentistry attracted more than 100 dentists, physicians, and athletic trainers to the first Sports Dentistry Symposium at the University of Texas Health Science Center at San Antonio.(142) Attendees of the symposium founded the Academy of Sports Dentistry on June 25, 1983.(69,143) The purposes of the organization were stated as follows: "To promote the advancement of research in all sciences pertaining to sports dentistry and its relationship to the body as a whole, the utilization of this knowledge for the promotion of better approaches to the prevention and the treatment of athletic injuries and oral disease, and the improvement of communication and cooperation among the members in order to share and utilize this knowledge for the benefit of the people."(143)

During the mid 1980s, researchers sought additional improvements in performance, comfort, and protection.(144)

In 1984, Morrow et. al. addressed the issue of speech intelligibility and player preference. Results of the study indicated that speech intelligibility was significantly better with custom mouth guards. Furthermore, signal callers preferred custom mouth protectors over mouth-formed varieties.(145)

In 1986, Kuebker et. al. published the results of an investigation designed to determine whether available mouth-formed mouth protectors satisfied the NCAA requirements for mouth guard use in football. Results indicated that for a significant number of university football players (85%), available mouth-formed mouth protectors were not large enough to meet NCAA specifications.(24)

In addition to continued research and development, the dental profession also sought to expand the coverage of mouth protectors to include other sports.

Results of a study by Garon et. al. indicated that 52 per cent of oral injuries and 38 per cent of concussions were reported in sports other than organized football. Baseball, basketball, and unorganized football were among the injury leaders.(132)

A survey of high school basketball players in the State of Florida indicated that 31 per cent of varsity players reported orofacial injuries during the 1986-1987 season. In many instances, a player suffered more than one injury during the season. Furthermore, data indicated that players not wearing mouth protectors were 6.8 times more likely to sustain oral injury than players who did wear protective guards.(66)

Increasing attention also was given to women's sports during this period. Although females participated in a

variety of physical contact sports, mouth protection programs were conspicuously absent in the vast majority of them. Therefore, dentists were urged to make every effort to bring mouth protection for female athletes up to the successful level attained for men.(51)

Currently, it appears that progress is being made towards that end. Mandatory mouth guard programs are now in effect in a number of women's sports programs.(13,15)

In addition, mouth protectors are being recommended for baseball, basketball, discus, gymnastics, martial arts, motocross, racquetball, rugby, shotput, skateboarding, skiing, skydiving, soccer, squash, surfing, trampolining, volleyball, and wrestling as well as other potentially injurious sports.(51,83,121)

#### ADDITIONAL USES FOR MOUTH PROTECTORS

Although the most common application of mouth protectors is in the reduction of sports-related injuries, mouth protectors are being used with increasing frequency in other areas of therapeutic and preventive dentistry and medicine.(22,146,147)

For years, custom mouth protectors have been used for daily home fluoride application. Fluoride applied in this manner has been shown to be highly effective in caries control.(148,149)

Mouth protectors also have been used to carry medications and prevent scar contraction in patients with intraoral chemical burns and electrical burns.(150,151)

An additional use of the custom mouth protector is the intraoral delivery of topical drugs. This method of delivery not only provides prolonged contact of the drug with the affected tissues, but often affords the protected tissues an added degree of comfort.(152)

Some authors have suggested the use of mouth protectors in the treatment of bruxism.(28,65,153)

Practitioners have cited the use of intraoral protective devices in the treatment of chronic lip irritation produced by musical instruments.(154-156)

In addition, mouth protectors have proven advantageous in a variety of oral surgical procedures. For instance, mouth protectors used as temporary covers can simplify oral surgery in patients with orthodontic appliances by preventing snagging and tearing of gloves.(157) Custom mouth protectors also have been used in the emergency treatment of excessive bleeding following the extraction of teeth.(158) And splinting of selected osseous fractures also has been accomplished using mouth protectors.(159)

Protectors have been used as removable splints to stabilize avulsed or displaced permanent teeth.(160,161)

Custom mouth protectors have been used successfully in preventing self-inflicted soft tissue damage in patients

with various neural and muscular disorders.(162-167)

In severely handicapped patients, mouth protectors have been used as oral orthotic devices.(102,168-170)

Custom mouth protectors are also used during dental management of head and neck cancer patients who are receiving radiation therapy. For these patients, protectors may be used in the placement of radium needles and in the application of topical fluoride.(22,171,172)

Numerous practitioners have advocated the use of mouth protectors to prevent hard and soft tissue injury during tracheal intubation and endoscopy.(173-179)

Mouth protectors have even been used to quantify changes in the contours of residual ridges.(180) This technique may prove quite valuable in the evaluation and treatment of intraoral implant patients.

Most recently, custom mouth guards have been recommended for shielding sensitive teeth during restorative treatment procedures.(181)

### III. RESEARCH OBJECTIVES

The objectives of this investigation were:

1. To characterize work of breathing during exercise in patients without intraoral mouth protectors in place.
2. To characterize work of breathing during exercise in patients with intraoral mouth protectors in place.
3. To determine whether intraoral mouth protectors significantly affect work of breathing during exercise.
4. To determine if certain classes of mouth protectors affect work of breathing more than others.

#### IV. METHODS AND MATERIALS

##### RECRUITMENT AND CONSENT PROCEDURES

Subject recruitment occurred via notices posted at the University of Texas at San Antonio Health Science Center. Verbal and written explanations of the investigative procedure were presented to each prospective participant. Questions were answered prior to participation. Signed consent forms were obtained from all subject-volunteers. Consent forms were maintained by the principal investigator.

##### SUBJECT POPULATION

In this investigation, eight normal subject-volunteers were studied. Subject-volunteers were males between the ages of 18 and 35.

Exclusion criteria included lung disease, inability to ambulate for any reason, history of cardiac disease, exertional chest discomfort, history of cardiac arrythmias, history of resting hypertension, severe arthritis, age less than 18 or greater than 35, medication use, nasal septal fractures, nasal septal deviations, nasal polyps, history of epistaxis or nasopharyngeal cancer, upper respiratory tract infections, swallowing disorders, peptic ulcer disease, previous gastro-esophageal surgery, lidocaine allergy,

any type of neuromuscular disease, and any pulmonary or other serious infections.

Physical statistics for all subject-volunteers are presented in Table 1, page 25.

#### MOUTH PROTECTORS - ACQUISITION, CONSTRUCTION, AND FITTING

Three distinct types of mouth protectors were used in this investigation. The following protectors were chosen based upon classification, availability, and structural design properties:

- 1) Mouth-formed, maxillary arch

Safe Play Manufacturing Co., Inc.

Sidney, Nebraska

(see Figure 1, page 26)

- 2) Mouth-formed, maxillary/mandibular arch

Tuf-Wear

Sidney, Nebraska

(see Figure 2, page 27)

- 3) Custom-formed, maxillary arch

(see Figure 3, page 28)

Each subject-volunteer was issued one mouth guard of each type.

TABLE 1DESCRIPTION OF SUBJECT POPULATION

Subject number	Age (years)	Race	Sex	Height (inches)	Weight (pounds)
1	27	Black	M	65	159
2	25	Hispanic	M	65	160
3	22	Caucasian	M	72	180
4	24	Caucasian	M	71	198
5	22	Hispanic	M	69	170
6	31	Caucasian	M	74	160
7	25	Caucasian	M	65	148
8	24	Asian-American	M	63	144

FIGURE 1

Mouth-Formed Maxillary Arch Mouth Protector

FIGURE 2

Mouth-Formed Maxillary/Mandibular Arch Mouth Protector

FIGURE 3

Custom-Formed Maxillary Arch Mouth Protector

Individual participants were directed to fit their own mouth-formed guards according to manufacturer's directions.

Custom-formed mouth guards were constructed and fitted according to the method presented by Morrow et. al.(88) For the purposes of this investigation, faceguard attachment tabs were excluded. Buccal and labial borders were kept 3mm short of vestibule and frenae extensions. Palatal extensions were kept 3mm from gingival margins of the teeth and were bevelled. Mouth protectors were extended to the distal aspect of maxillary second molars. Maxillary third molars, when present, were not covered. All steps in the construction and fitting of the custom formed mouth guards were performed by the principal investigator.

#### EXPERIMENTAL DESIGN AND METHODS

Eight subject-volunteers were chosen to participate in this study based upon the criteria presented in the "Subject population" section. Subject-volunteers ranged from 18 to 31 years of age. None of the participants reported any known physical compromise.

Individuals were informed that testing would be conducted in the Pulmonary Function and Exercise Laboratories of the Audie Murphy Memorial Veterans' Administration Hospital. Specific reporting instructions were provided for each of the subject-volunteers. Not more

than one subject-volunteer was scheduled for testing on a given day.

Upon arrival at the Pulmonary Function and Exercise Laboratories, testing procedures were reviewed with the participant. In addition, each subject-volunteer was provided with a tour of the laboratories and an explanation of the equipment to be employed during the investigation.

Spirometry (testing of the maximum air capacity of the lungs) was performed on each subject prior to further investigative procedures. Results were evaluated to rule out underlying respiratory disease. Subject-volunteers were permitted to continue only if spirometry values were determined to be within normal limits. Representative spirometry results are presented in Table 2, page 31.

Experimental design required the presence of an esophageal balloon catheter during the testing procedure. For the purposes of this study, the catheter was introduced via the nasal route.

In order to facilitate placement of the catheter, a 2% xylocaine gel was applied to the nasal passages of the subject-volunteer. Following application of the xylocaine gel anesthetic, a 1.7mm diameter, 50cm long polyethylene catheter with a 10cc latex balloon was passed through the nasal passages and into the mid-esophagus. The external portion of the catheter was fixed to prevent its' movement during the investigative procedure.

TABLE 2

## REPRESENTATIVE SPIROMETRY RESULTS

Spirometry		Actual	%Pred	Predicted
FVC	(L)	5.72	96	5.94
FEV1	(L)	4.94	108	4.56
FEF25-75%	(L/S)	5.45	118	4.59
FEFmax	(L/S)	11.34	111	10.17
FEV1/FVC	(%)	86.27	112	76.74
FIVC	(L)	5.53		
FIV.5	(L)	2.73		
FIV1	(L)	5.45		
PIFR	(L/S)	6.94		

Following the placement of the esophageal catheter, the subject-volunteer was directed to sit quietly for five minutes. This period allowed the participant to become accustomed to the esophageal catheter.

During this interval, the participant's respiratory rate, heart rate, and blood pressure were monitored. Values were recorded to serve as the basis for subsequent comparison.

When these values had been obtained, the participant was prepared for exercise. Electrocardiogram (ECG) leads were attached. A trial strip was generated to ensure proper function.

An electronic sphygmomanometer was used to monitor blood pressure at one minute intervals.

Following the attachment of these monitoring devices, the patient was told to be seated astride the bicycle ergometer. Monitoring systems again were examined to verify proper function.

Accurate assessment of respiratory parameters required that inhalation and exhalation occur entirely via the oral pathway. Therefore, prior to the initiation of the exercise protocol, an occluding clip was placed on the subject's nose.

The subject-volunteer then was assigned one of the following independent variables:

- 1) No mouth protector (control measurement)
- 2) Mouth-formed maxillary arch mouth protector
- 3) Mouth-formed maxillary/mandibular arch mouth protector
- 4) Custom-formed maxillary arch mouth protector

The order of assignment was determined via random sequence.

Following the placement of the appropriate mouth protector (no mouth protector in the control measurement), the subject-volunteer was asked to perform a predetermined level of constant-workrate bicycle ergometer exercise.(182,183)

The protocol involved 10 minutes of exercise at 40 per cent of the predicted maximum workload.(184) Calculation of predicted maximum workload for the individual was performed based upon the following formula:

$$\begin{aligned}\text{MAXIMUM WORK (in watts)} &= (3.33 \times \text{height in centimeters}) \\ &\quad - (1.42 \times \text{age in years}) \\ &\quad - (46.9 \times \text{gender value}) \\ &\quad - 311.2 \text{ watts}\end{aligned}$$

(In which gender values are: Male = 0, Female = 1)

Upon determination of maximum workload values, the desired 40 per cent figure was calculated arithmetically (see Table 3, page 34).

TABLE 3CALCULATED WORKLOADS FOR EXERCISE PROTOCOL

Subject number	Height (inches)	Height (cms)	Age (years)	Sex	Predicted maximum workload (watts)	40% Predicted maximum workload (watts)
1	65	165	27	M	200	80
2	65	165	24	M	204	82
3	72	183	22	M	267	107
4	71	180	24	M	254	102
5	69	175	22	M	240	96
6	74	188	31	M	271	108
7	65	165	25	M	202	81
8	63	160	24	M	188	75

Calculations performed using the formula:

MAXIMUM WORK (in watts) = (3.33 x height in centimeters)

- (1.42 x age in years)

- (46.9 x gender value)

- 311.2 watts

(In which gender values are: Male = 0, Female = 1)

Resultant workloads were expressed in watts. Desired wattages were entered into the bicycle ergometer's on-board computer. With this information provided, the bicycle ergometer automatically adjusted pedaling resistance to match the desired workload.

During exercise, the subject-volunteer breathed through a large-volume oral mouthpiece similar to a scuba mouthpiece.

While the subject-volunteer was exercising under these conditions, the investigators continuously monitored: 1) Intrathoracic pressure with an esophageal balloon catheter connected to a  $\pm 50$  cms H<sub>2</sub>O differential pressure transducer with a 10 Hz response characteristic, and 2) Airflow at the mouth with a linear pneumotachograph of  $\pm 6$  liters per second range.

Sampling of these parameters was accomplished in 30-second time blocks. Sampling was initiated when the investigators determined that a steady metabolic state had been reached by the subject-volunteer (described below). An additional 30-second sample was initiated one minute later to verify reproducibility of the measurements.

Representative results are displayed in Table 4, page 36.

All values were recorded on computer disks to facilitate subsequent data analysis.

Invasive measurements made during exercise were limited to esophageal (intrathroacic) pressures. These measurements

TABLE 4REPRESENTATIVE RESPIRATORY RECORDING DATA

RODNEY PHOENIX, EXERCISE, CUSTOM-FORMED MOUTH PROTECTOR

TIME (sec)	FLOW (liters/sec)	VOLUME (liters)	ESOPHAGEAL PRESSURE (cmH <sub>2</sub> O)
0.00	-0.98	1.03	-6.09
0.10	-1.41	0.91	-8.08
0.20	-1.57	0.76	-11.82
0.30	-1.66	0.60	-12.18
0.40	-1.75	0.43	-12.65
0.50	-1.90	0.24	-13.06
0.60	-1.75	0.06	-14.22
0.70	-1.69	-0.11	-15.14
0.80	-1.73	-0.28	-15.51
0.90	-1.85	-0.46	-15.78
1.00	-1.55	-0.63	-17.72
1.10	-1.19	-0.77	-19.80
1.20	-1.20	-0.89	-21.51
1.30	-0.94	-0.99	-20.72
1.40	-0.63	-1.07	-19.85
1.50	-0.50	-1.13	-22.48
1.60	-0.35	-1.17	-25.20
1.70	-0.13	-1.19	-22.89
1.80	0.02	-1.20	-19.29
1.90	0.10	-1.20	-23.49
2.00	0.23	-1.19	-24.37
2.10	0.42	-1.16	-21.42
2.20	0.90	-1.09	-16.06
2.30	1.38	-0.98	-15.00
2.40	1.64	-0.83	-11.08
2.50	1.92	-0.65	-7.34
2.60	2.08	-0.45	-5.54
2.70	2.33	-0.23	-4.34
2.80	2.33	0.00	-3.23
2.90	1.85	0.21	-3.23
3.00	1.51	0.38	-3.23

NOTE: This sample represents 3 seconds of respiration.

were determined using one polyethylene catheter as described above.(185)

Noninvasive measurements made during exercise included: minute ventilation, oxygen consumption, carbon dioxide production, end-tidal  $pO_2$  and  $pCO_2$  using a sensormedics metabolic cart. Monitored values were printed at 30-second intervals (see Table 5, page 38). These noninvasive parameters were used to demonstrate that the subject was exercising at a constant metabolic state. As a result, any difference in the work of breathing should have been due to the resistance provided by the mouth protector rather than a variation in the experimental conditions.

The continuous, noninvasive monitoring of heart rate, heart rhythm and blood pressure were employed as a precautionary measure.(182,183)

As an additional precautionary measure, an ear oximeter was used to monitor arterial oxygen saturation.

Following the prescribed course of exercise, the mouthguard (none in the case of control measurement) was removed and the participant was instructed to rest for a period of 20 minutes. Respiratory rate, heart rate, and blood pressure were monitored. Comparisons were made to ensure that all values had returned to pre-exercise levels.

When the allotted time had passed, another independent variable was assigned for testing. The subject-volunteer was directed to repeat the exercise protocol.

TABLE 5REPRESENTATIVE METABOLIC DATA**REAL-TIME REPORT**

NAME: Rodney Phoenix  
ID NUMBER: 0738

DATE: Mar 16, 1988  
TIME: 10:35  
PRESET NAME: Pulm Ex

Time	VE BTSPS	VT	f	Heart Rate	VO2 STPD	VCO2 STPD	RER
min	L/min	L;br	br/min	bts/min	L/min	L/min	
0:00	9.6	0.856	11.2	60	0.362	0.242	0.67
0:30	14.1	0.999	12.1	78	0.678	0.441	0.85
1:00	18.4	1.038	17.8	100	0.949	0.610	0.64
1:30	19.5	1.283	15.2	116	1.146	0.730	0.66
2:00	26.7	1.535	17.4	123	1.345	1.020	0.72
2:30	31.8	1.611	19.7	128	1.650	1.375	0.83
3:00	34.7	1.578	22.0	129	1.710	1.530	0.89
3:30	40.0	1.986	20.1	128	1.684	1.656	0.98
4:00	38.9	1.930	20.1	129	1.688	1.672	0.99
4:30	39.1	1.930	20.2	128	1.684	1.670	0.99

END OF PAGE 1

\*NOTE: At 3:30 minutes, all parameters have entered a plateau phase. This is designated a "steady metabolic state."

The procedure was repeated until all independent variables had been tested.

Subsequently, results were used to calculate mean esophageal pressures for each individual exercising under each condition.

Because mean esophageal pressure is an analog of flow-resistive work of breathing per liter minute ventilation, this measurement was used as the basis for analysis. The use of mean esophageal pressure as an index of work of breathing is commonly accepted in pulmonary function studies.(186)

## V. RESULTS

Mean esophageal pressures were determined from data collected while each subject-volunteer was exercising and breathing with:

- 1) No mouth protector, to serve as the control measurement.
- 2) Each of three types of commonly available mouth protectors evaluated separately and in random sequence.

Results were categorized according to the independent variable being tested (i.e. no mouth protector, mouth-formed maxillary/mandibular arch mouth protector, custom-formed maxillary arch mouth protector, and mouth-formed maxillary arch mouth protector).

Individual means were calculated electronically via computer software program (Courtesy Dr. Jason Bates, Meakins-Christie Laboratories, McGill University, Montreal, Canada). The results are displayed in Table 6, page 41.

Using the values determined for individual participants, group statistics were calculated. Group means, standard deviations, and standard errors are presented in Table 7, page 42.

TABLE 6

MEAN ESOPHAGEAL PRESSURES MEASURED DURING STEADY STATE  
EXERCISE  
 (expressed in cmH<sub>2</sub>O)

Subject number	Control (no mouth protector)	Mouth-formed maxillary/ mandibular arch mouth protector	Custom-formed maxillary arch mouth protector	Mouth-formed maxillary arch mouth protector
1	4.8	7.1	10.9	7.1
2	7.1	11.9	11.4	14.3
3	4.5	4.9	8.2	8.9
4	8.0	8.9	8.6	8.7
5	7.1	6.8	9.4	9.4
6	4.4	10.4	10.4	10.8
7	5.4	7.7	6.4	8.4
8	3.1	4.6	6.4	5.5

TABLE 7MEASURES OF CENTRAL TENDENCY AND DISPERSION

Independent variable	Mean	Standard deviation	Standard error
Control (no mouth protector)	5.5500	1.6826849	0.5949190
Mouth-formed maxillary/mandibular arch mouth protector	7.7875	2.5334547	0.8957115
Custom-formed maxillary arch mouth protector	8.9750	1.9144190	0.6768493
Mouth-formed maxillary arch mouth protector	9.1375	2.6092897	0.9225232

When rank ordered from least numerical value to greatest numerical value, mean esophageal pressures assumed the following sequence:

- 1) Control  
(no mouth protector) - Group mean 5.5500 cmH<sub>2</sub>O
- 2) Mouth-formed  
maxillary/mandibular arch  
mouth protector - Group mean 7.7875 cmH<sub>2</sub>O
- 3) Custom-formed  
maxillary arch  
mouth protector - Group mean 8.9750 cmH<sub>2</sub>O
- 4) Mouth-formed  
maxillary arch  
mouth protector - Group mean 9.1375 cmH<sub>2</sub>O

In order to determine if a statistically significant difference existed between the group means, the repeated-measures analysis of variance (ANOVA) was used.(187) Results of this design revealed a significant difference at the 0.05 level (see Table 8, page 44).

Although the repeated-measures analysis of variance revealed an inequality, ANOVA designs do not indicate which groups differ from one another. To determine the exact nature of these differences, Fisher's least significant difference analysis was employed.(188) The results of Fisher's least significant difference analysis are shown in Table 9, page 45.

TABLE 8ANALYSIS OF VARIANCE PROCEDURE

Dependent variable: Mean esophageal pressure

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	10	161.8175	16.1817500	8.10	0.0001
Error	21	41.9775	1.9989286		
Corrected Total	31	203.7950			

R-Square	C.V.	Root MSE	Esophageal Pressure Mean
0.794021	17.98200	1.413835	7.86250000

Source	DF	Anova SS	Mean Square	F Value	Pr > F
SUBJECT	7	96.0850	13.72642857	6.87	0.0003
TREATMENT	3	65.7325	21.91083333	10.96	0.0002

TABLE 9FISHER'S LEAST SIGNIFICANT DIFFERENCE ANALYSIS

NOTE: This test controls the type I comparisonwise error rate, not the experimentwise error rate.

Alpha = 0.05    df = 21    MSE = 1.998929

Critical Value of T = 2.08

Least Significant Difference = 1.4701

Means with the same letter are not significantly different.

T Grouping	Mean	Number	Treatment
A	9.138	8	Mouth-formed maxillary arch mouth protector
A	8.975	8	Custom-formed maxillary arch mouth protector
A	7.787	8	Mouth-formed max/man arch mouth protector
B	5.550	8	Control (no mouth protector)

Examination of the values presented in Table 9 indicates two distinct T groupings (designated by the letters A and B). By definition, means with the same letter designation are not significantly different. However, means with different letter designations are significantly different. Therefore, the mean esophageal pressure for control (no mouth protector) differed from all remaining treatments (i.e. mouth-formed maxillary/mandibular arch mouth protector, custom-formed maxillary arch mouth protector, and mouth-formed maxillary arch mouth protector). Furthermore, the mean esophageal pressures for the custom-formed mouth protector and both mouth-formed mouth protectors were statistically similar.

Two additional parameters were measured and recorded. These were rate of breathing and mean tidal volume.

Values for rate of breathing during steady state exercise are presented in Table 10, page 47. Using these values, group means were calculated. The repeated-measures analysis of variance was used to determine if a significant difference existed at the 0.05 level. ANOVA revealed no difference in the means of these groups.

Mean tidal volumes recorded during steady state exercise are presented in Table 11, page 48. Group means were calculated. The repeated-measures analysis of variance was used to determine if a statistically significant difference existed at the 0.05 level. ANOVA revealed no

TABLE 10

RATE OF BREATHING DURING STEADY STATE EXERCISE  
 (expressed in liters/minute)

Subject number	Control (no mouth protector)	Mouth-formed maxillary/ mandibular arch mouth protector	Custom-formed maxillary arch mouth protector	Mouth-formed maxillary arch mouth protector
1	15.5	15.9	14.9	15.1
2	17.7	17.0	17.8	17.8
3	22.0	20.8	22.8	21.6
4	16.9	16.2	16.7	16.9
5	16.8	16.5	16.9	16.4
6	22.2	22.4	22.3	22.7
7	18.0	18.2	18.3	18.0
8	23.8	26.0	22.9	24.2
MEAN	19.1125	19.1250	19.0750	19.0880

ANOVA reveals no statistically significant difference at the 5% level.

TABLE 11

MEAN TIDAL VOLUMES RECORDED DURING STEADY STATE EXERCISE  
(expressed in liters/breath)

Subject number	Control (no mouth protector)	Mouth-formed maxillary/ mandibular arch mouth protector	Custom-formed maxillary arch mouth protector	Mouth-formed maxillary arch mouth protector
1	2.061	2.226	2.270	2.316
2	1.685	1.813	1.696	1.695
3	2.055	1.995	1.972	1.975
4	2.233	2.607	2.315	2.267
5	2.756	2.833	2.727	2.782
6	1.972	2.110	1.955	1.961
7	1.789	1.757	1.641	1.873
8	1.334	1.235	1.258	1.246
MEAN	1.985625	2.072000	1.979250	2.014375

ANOVA reveals no statistically significant difference at the 5% level.

statistically significant difference in the means of these groups, either.

## VI. DISCUSSION

A review of the literature indicates that all investigations concerning the effects of mouth protectors upon work of breathing have been subjective.(1-5) Furthermore, the results of the investigations have been mixed.

A report of the Bureau of Dental Health Education and Bureau of Economic Research and Statistics of the American Dental Association compared the effects of mouth protectors upon ease of breathing. Results indicated, "Some interference with breathing was experienced by 21 per cent of the players while wearing the custom-made mouth protectors, 44 per cent while wearing the mouth-formed, and 51 percent while wearing the stock type."(2)

A survey of Texas high school football players conducted by J.M. Gee indicated that among reasons given by players for not wearing mouth protectors, nearly half (47.6 per cent) cited difficulty in breathing as a contributing factor.(3)

Somewhat later, a study by deWet indicated that only about 4 per cent of subjects experienced difficulty in breathing while wearing mouth protectors.(5)

Despite the wide range of results obtained in these surveys, little was done to establish clinical correlations between the presence of mouth protectors and resultant

changes in the work of breathing.

Apparently, the only clinical investigation related to this subject was performed by Luke et. al. in 1981. These investigators conducted a pilot study to determine the effects of mouth protectors not upon work of breathing, but upon airflow. Although their investigation indicated that mouth protectors significantly affected airflows at low work levels, it appears that no follow-on investigations were performed.(141)

The current study was undertaken as a result of the need for objective clinical information regarding the effects of mouth protectors upon work of breathing. Investigative design employed mean esophageal pressure as an index of work of breathing. The use of mean esophageal pressure for this purpose is commonly accepted in pulmonary function studies.(186) The mathematical basis for this design is as follows:

$$\text{WORK OF BREATHING} = \text{MEAN ESOPHAGEAL PRESSURE} \times \text{MINUTE VENTILATION}$$

Since minute volume may be defined by the formula,

$$\text{MINUTE VENTILATION} = \text{RATE OF BREATHING} \times \text{MEAN TIDAL VOLUME}$$

then,

$$\text{WORK OF BREATHING} = \text{MEAN ESOPHAGEAL PRESSURE} \times \text{RATE OF BREATHING} \times \text{MEAN TIDAL VOLUME}$$

Therefore, if the rate of breathing and the mean tidal volume remain relatively constant, then the mean esophageal

pressure should vary in direct proportion to the work of breathing.(186)

A review of statistical information presented in Tables 10 and 11 indicates that both of the aforementioned parameters displayed a high level of consistency. As a result, the mean esophageal pressures should provide accurate indices of the work of breathing.

A review of mean esophageal pressures for individual participants (see Table 6, page 41) permits certain observations. For each subject-volunteer, the control treatment (no mouth protector) consistently exhibited the smallest mean esophageal pressure. Among the mouth protector treatments, an evident pattern of statistical superiority was not observed. This indicates that intra-subject factors may play a significant role in the determination of mouth-protector performance. For instance, a perceived discrepancy in the fit or overall comfort of a particular mouth protector may contribute to the alteration of mandibular posture or tongue position. Either of these factors could produce a decreased oral airway space and, consequently, increased airway resistance and increased work of breathing.

Following the observation of individual mean esophageal pressures, group statistics were calculated. Group means were rank ordered according to increasing esophageal pressure values. In doing so, it was observed that the

control treatment (no mouth protector) possessed the smallest numerical value. Control was followed by the mouth-formed maxillary/mandibular arch mouth protector. Afterwards came the custom-formed maxillary arch mouth protector. And, finally, the mouth-formed maxillary arch mouth protector which possessed the greatest numerical value.

Certainly, it was not surprising that control possessed the mean esophageal pressure of smallest numerical value. A totally unobstructed airway would be expected to provide the least resistance to respiratory efforts.

The fact that control was followed by the mouth-formed maxillary/mandibular arch mouth protector was somewhat surprising. It seemed that the fixed-volume ventilation ports which traversed the anterior aspect of this mouth protector would provide a tremendous hindrance to respiration. Consequently, this mouth protector was expected to provide more resistance than either of the single-arch mouth protectors (i.e. custom-formed maxillary arch mouth protector and mouth-formed maxillary arch mouth protector).

Two possible explanations are offered for the results observed in this portion of the investigation. The first explanation involves the encroachment of certain mouth protectors upon the participant's "free-way space" (The distance between the occluding surfaces of the maxillary and

mandibular teeth when the mandible is in its physiologic rest position). In order to minimize the incidence of oral injury, a mouth protector must provide an interocclusal portion designed to prevent traumatic contact of the occlusal surfaces. In the case of a single-arch mouth protector, this involves the adaptation of a resilient material over a cast of the patient's arch or directly over the teeth in the patient's mouth. With the introduction of this material, we are encroaching upon the patient's free-way space. Consequently, additional resistance may be introduced at the level of the oral airway. Such an increase in oral airway resistance is likely to produce a resultant increase in the work of breathing.

Unlike single-arch designs, the maxillary/mandibular mouth protector does not depend upon free-way space for efficiency of ventilation. Instead, the maxillary/mandibular design incorporates two breathing ports into the anterior aspect of the interocclusal protective layer. These fixed-volume ports allow the passage of air, independent of interocclusal distance (free-way space). Therefore, one must consider the possibility that the total volume of the breathing ports in patients wearing the maxillary/mandibular mouth protector exceeded the total volume of the anterior free-way space in participants wearing single-arch protectors.

A second possibility involves the effects of mouth protectors upon upper airway posture. Because the single-arch designs did not exceed the interocclusal distance, it is assumed that they produced no significant change in upper airway posture. Conversely, the maxillary/mandibular design appeared to create a greater interarch dimension and to cause anterior positioning of the mandible. These factors may have produced an alteration of the upper airway similar to that produced by the "chin lift" employed in cardiopulmonary resuscitation techniques. Such a change in upper airway posture could conceivably account for decreased resistance and decreased work of breathing.

Following the examination and ordering of group means, a statistical comparison of these means was performed. Due to investigative design, the repeated measures analysis of variance (ANOVA) was employed. Results of this analysis revealed a significant difference at the 0.05 level (see Table 8, page 44). Although the repeated-measures analysis of variance indicated a significant difference, ANOVA designs do not specify which means differ from one another. Consequently, Fisher's least significant difference analysis was used to determine the exact nature of these differences (see Table 9, page 45).

The results of Fisher's least significant difference analysis indicated two distinct T groupings, designated by the letters A and B. By definition, means with the same

letter designation are not significantly different. However, means with dissimilar letter designations are significantly different. Therefore, the mean esophageal pressure for control (no mouth protector) differed from all mouth protector treatments. In addition, the mean esophageal pressures for the custom-formed mouth protector and both mouth-formed protectors were statistically similar.

Physiologically, it seems reasonable that a patient exercising and breathing without a mouth protector would experience less difficulty in respiration than a patient exercising and breathing with a mouth protector in place. Therefore, statistical evidence indicating a significant difference between these conditions was readily accepted.

The statistical parity of mouth-protector treatments was unexpected. Previous investigations indicated that custom-formed mouth protectors provided less interference with breathing than did mouth-formed varieties.(1,2) However, one must consider that these investigations were based upon surveys, and not the results of physiologic measurements. In addition, the aforementioned investigations were conducted several years ago. Subsequent advances in materials and designs have permitted substantial improvements in mouth-formed protectors.

The need for further advances in materials and designs is accompanied by a need for relevant clinical investigations into the physiological effects produced by

commonly-used mouth protectors. This investigation was undertaken to provide objective results in one previously unexplored area. Future research is suggested to determine the effects of mouth protectors upon upper airway posture, respiratory muscle fatigue, and overall exercise performance. Additional mouth protector investigations should be directed at structural alterations designed to minimize adverse physiological effects. In this manner maximum athletic performance with maximum protection can be achieved.

## VII. SUMMARY

A clinical investigation was undertaken to determine the effects of commonly-used athletic mouth protectors upon work of breathing during exercise. Results of the investigation indicated a significant increase in work of breathing when intraoral mouth protectors were used. Statistical analyses did not indicate a significant difference between the three types of mouth protectors utilized in this investigation.

APPENDIX

PATIENT CONSENT FORM

INFORMATION ABOUT EFFECTS OF ATHLETIC MOUTH PROTECTORS UPON  
WORK OF BREATHING DURING EXERCISE  
AUDIE L. MURPHY MEMORIAL VETERANS' ADMINISTRATION HOSPITAL

You are being asked to take part in a research study of the effects of athletic mouth protectors upon breathing. We want to learn whether mouth protectors make it harder to breathe during exercise. You are being asked to take part in this research study because you are a normal, healthy person.

If you decide to take part, we will ask you to spend approximately four hours undergoing breathing and exercise tests in the Pulmonary Function Laboratory. All breathing and exercise tests will take place during the same day. Exercise testing will be divided into four parts (phases). All parts will be very much alike. First, we will ask you to arrive at the Pulmonary Function Laboratory at a specified date and time. Next, we will ask you to sniff a teaspoon of numbing jelly, called xylocaine, into your nostrils. After the inside of your nose becomes temporarily numb, we will pass a thin flexible tube (catheter) through one of your nostrils and into your esophagus (the food tube between your mouth and stomach). Then you will be asked to exercise by pedaling on a stationary bicycle. During one phase of testing, you will be asked to exercise without a mouth protector in your mouth. During another phase, you will be asked to exercise with one type of mouth protector in your mouth. During a third phase, you will be asked to exercise with a different type of mouth protector in place. And during the final phase, you will be asked to exercise with the remaining mouth protector in place. Therefore, by the end of the fourth phase you will have exercised with each of three different mouth protectors in place, and one phase with no mouth protector in place. The mouth protector which you wear during a particular phase will be determined in a random manner similar to the flip of a coin. During each phase of exercise, we will ask you to pedal the bicycle for a total of 10-12 minutes. During this bicycle exercise you will pedal against a predetermined level of resistance. While you are pedaling, we will measure how well you move air in and out, and how well your breathing muscles work by having you breathe through a device much like a scuba diver's mouthpiece. Your heart rate will be continuously monitored, and your blood pressure checked every minute during exercise. The small, flexible tube (catheter) will be left in place until all phases of testing have been completed.

Although some of these breathing tests such as the small tube through the nostril are used by doctors in everyday clinical situations, some discomfort can be regularly expected. Patients often experience some nasal irritation from the numbing jelly, as well as some occasional gagging during the passage of the small tube (catheter). Occasional nausea with rare vomiting can occur.

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Signature of subject

INFORMATION ABOUT EFFECTS OF ATHLETIC MOUTH PROTECTORS UPON  
TOTAL PULMONARY RESISTANCE

Leg fatigue, general tiredness and shortness of breath regularly occur with bicycle exercise. Rarely, subjects experience dizziness, fainting, the need for hospitalization and treatment, or death when exercise occurs. We expect this to be extremely unlikely in a normal person. You will be monitored very closely during all procedures. If you are injured as a result of being in the study, emergency medical care will be provided free. If you need additional medical care for the injury, you will have to pay for all charges. We are not able to give you money if you are injured.

We do not anticipate any direct benefits to you if you decide to participate in this study. However, helpful information about the use of mouth protectors will be obtained and this information could be useful for athletes and athletic programs throughout the United States.

In recognition of your time and effort, you will be paid \$50 for completion of this study. There will be a one week delay in receipt of payment.

Everything we learn about you in the study will be confidential. If we publish the results of the study in a scientific journal or book, you will not be identified in any way.

Your decision to take part in this study is voluntary. You are free to decide not to take part in this study or to stop the study at any time. If you decide not to take part in this study or to stop the study, it will not affect your future medical care at the Audie Murphy Memorial Veterans' Administration Hospital or The University of Texas Health Science Center at San Antonio.

If you have any questions now, feel free to ask us. If you have additional questions later, Dr. Rodney Phoenix can be reached at 567-6160 or at home 521-4147, and Dr. William Gibbons at 696-9660, ext. 4743 or at home 696-6735. The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject (567-1350).

You will be given a copy of this form to keep.

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Signature of subject

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Date

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(Time)

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